VI. Comments Recommending Actions EPA Should Take

Comment were received recommending actions that the EPA should take with regard to the request for an EUP to allow testing of OX5034. Some commenters requested an extension of the comment period allotted for the Notice of Receipt for requesting an EUP for OX5034. Some comments urged the Agency to greater transparency. Other comments requested that EPA allow an additional opportunity for the public to comment on the request.

A. Extend the Comment Period

Five commenters requested an extension of the comment period allotted for the Notice of Receipt for an application requesting an EUP to evaluate the efficacy of releasing male OX5034 as a tool to suppress wild Aedes aegypti mosquito populations. (0038, 0326, 0344, 0243, 0290).

The Center for Food Safety (0344) stated that:

> "EPA should extend the comment period until the EPA and Oxitec can provide the public a more adequate set of data to review. At the very least, the public should be able to review all data generated from any caged trials of the new Oxitec OX5034 strain of the GE mosquito in any country. Oxitec should provide complete genomic sequence of the OX5034 strain, including both the intended genetic engineering and any off-target effects of the engineering. Oxitec provides no evidence that the female-killing mechanism engineered into the OX5034 strain is 100% effective. It is essential that such evidence is published and made available for independent scrutiny and consultation in order to assess the risk of release of female GE mosquitoes in the proposed experiments. Oxitec should provide all data on the survivability of the OX5034 strain, including how many females might have escaped from the caged confinement. If Oxitec has not studied which other *Ades* species and which other *Ades aegypti* strains the OX5034 strain can hybridize with after release, such experiments need to be required given recent reports of its earlier strain hybridizing with wild type *A. aegypti*."[1] (Center for Food Safety 0344 p. 3)

Commenter B. Wray (0038) stated that:

> "The brevity of the comment period adds risk to the review process, and we ask that a reasonable extension of 60 days be granted to permit proper investigation and response

[1] https://www.sciencemag.org/news/2019/09/study-dna-spread-genetically-modified-mosquitoes-prompts-backlash

> to be accumulated from a broad array of sources. Without great objective input, novel advanced technology cannot be properly vetted prior to use." (B. Wray 0038 p.1)

Commenter B. Wray (0038) furthered the argument stating that:

> "After repeated visits to Regulations.gov the Docket still only has the EPA instructions and a general letter that suggests the available performance data is limited to a marketing document making claims with no measured quantified documented results to support Oxitec's performance claims. There is no long terms analysis on the actual reproductive legacy, genetic heredity, introgression and hybridization of other wild type species. In the wake of the Yale study[NOTEREF _Ref30598723 \h * MERGEFORMAT], no releases of any Oxitec genetically modified species should be permitted without complete understanding of all unintended off-site mutations. Assays of a statistically significant sample set of the OX5034 should be performed to understand off target genetic mutations as part of the technical review to assure experimental use of the technology is safe." (B. Wray 0038 p. 2)[Reference inserted]

Commenter B. Wray (0038) specifically noted that:

> "Zero analysis exists with regard to antibiotic resistant bacterial promotion." (B. Wray 0038 p. 1)

Commenter B. Wray (0038) concluded by stating:

> "Please advise if there is actual scientific data available on the OX5034. This is a gene-drive species and much greater risk of evolutionary consequences are associated with any release. We request much greater testing and documentation of the science and performance of the OX5034. In light of the survival of the OX513A, we must have proof of what the OX5034 survival rates are for females. Prove it is safe!" (B. Wray 0038 p. 2)

GMO Free USA (0326) requested an extension of the public comment period for an additional 90 days arguing that 30 days is simply not enough to evaluate the complexity and impacts of this proposal:

> "1. New research has been published this week on the efficacy of a release of Oxitec's genetically engineered mosquitoes on mosquito populations in Brazil. The study, published by Yale University scientists in the journal Nature, documented unexpected and unintended consequences from the release.
> https://www.nature.com/articles/s41598-019-49660-6
> 2. The granting of this experimental permit has the potential, over time, to impact ecosystems across the country and those of neighboring countries. . . .
> 4. Extending the comment period is warranted due to the numerous legal, scientific and economic considerations contained within this proposal including potential allergenicity or other unintended effects on public health." (GMO Free USA 0326 p. 1)

B. Offer an Additional Opportunity for Public Comment

W. Jordan and A. Jones (0327) stated that:

> "Given the significance of the proposed EUP, we recommend that EPA open an additional round of comment that allows the public to see the proposal detailing the methods for evaluating efficacy under the EUP, together with EPA's scientific review of those methods." (W. Jordan and A. Jones 0327 p. 2-3)

Anonymous (0124), noting that several safety related points had not been addressed suggested that:

> "Oxitec be required to address these safety issues fully and then the public be given a further opportunity to comment." (Anonymous 0124 p. 1)

C. Ensure Transparency

Friends of the Earth (0342) stated that:

> "Because this is a new genetically engineered insect to be reviewed as a pesticide, the EPA must reveal its analysis of the environmental, health and social impacts of Oxitec's GE mosquito release proposal;" (Friends of the Earth 0342 p. 8)

The Center for Food Safety (0344) stated that:

> "No public information has been provided in the Docket or elsewhere relating to the survival rates of GE females to adulthood, in the presence or absence of sources of tetracycline: this makes it impossible to assess Oxitec's claim that no biting GE females will be released or survive to adulthood." (Center for Food Safety 0344 p. 2)

The Center for Food Safety (0344) stated that:

> "The documents provided to EPA for the docket include no details of Oxitec's proposed experimental program, and no environmental assessment (EA) or environmental impact statement (EIS) has been provided. The Center for Food Safety and a coalition of groups

> gave the FDA notice that the coalition planned to sue under the Endangered Species Act given the arbitrary and capricious environmental review performed by the FDA."[2]

Commenters M. Lopez () and J. Barton (0295) stated that:

> "Since this is the first genetically engineered insect to be reviewed as a pesticide, the EPA must reveal its analysis of the environmental, health and social impacts of Oxitec's GMO mosquito release proposal;" (M. Lopez p. 1; J. Barton 0295 p. 1)

Commenter M. Jones (0035) stated that while from "what I have learned about this issue, the procedure to find a way to attempt to downregulate the disease vector Aedes aegypti is a logically sound one overall":

> "I oppose implementation in the US; we need to be certain that the technology is reliable in field applications. I am very concerned that the timing also of this request is of such a short fuse that the issue will become largely unnoticed and the technology allowed to slip through and be implemented without sufficient public and scientific comment. . . . the research group must establish a stronger 'kill effect' and find ways to prevent the development of unforseen consequences." (M. Jones 0035 p. 1)[Typographical error in the original]

D. Seek Advice From Independent Committees of Experts

Several commenters (0342, 0176, 0344, 0335, 0295, 0316, 0320) argued that EPA should seek advice from independent experts.

Friends of the Earth (0342) stated that EPA should:

> "Have a committee of independent ecologists and entomologists, public health experts (including dengue fever and zika virus specialists), and other key experts and public stakeholders review the proposal from Oxitec;" (Friends of the Earth 0342 p. 8)

Friends of the Earth (0342) also argued that a full EIS prepared for OX5034 should be :

> " . . . reviewed by a committee of independent ecologists and entomologists, public health experts, and other key experts and public stakeholders."(Friends of the Earth 0342 p. 2)

[2] https://www.centerforfoodsafety.org/press-releases/4580/advocates-challenge-fda-on-first-ever-ge-mosquito-release

Friends of the Earth (0342) added that experts external to the Agency should also be present at meetings with the public for:

> " . . . review of the companys proposal . . . ;"

The Center for Food Safety (0344) and GeneWatch UK (0335) also called for the following to be supplied to the public:

> " Published criteria for assessing the impact of existing control measures and the proposed releases on the target pest and the risks of all the relevant diseases." (Center for Food Safety 0344 p. 18; GeneWatch UK 0335 p. 15-16)

M. Lopez () and J. Barton (0295) stated that:

> "EPA must form a committee of independent ecologists and entomologists, public health experts (including dengue fever and zika virus specialists), and other key experts and public stakeholders to review the proposal from Oxitec;" (M. Lopez p.1; J. Barton 0295 p. 1)

K. Gould (0320) demanded that:

> ". . . the EPA receive more expert opinion to make sure that this procedure is valid. If it isn't, then the EPA must abandon this proposal." (K. Gould 0320 p. 1)

E. Comments Arguing that the Agency Should Seek Public Input

Several commenters requested that the Agency seek public input into the decision making process. Some commenters requested that EPA convene meetings with the public, others proposed that a referendum be held.

Commenter Anonymous (0236), for example, stated that:

> "As an American citizen, I feel that it should not be up to a small group of people to decide what to release into my environment. I do not consent to this experiment that could potentially impact my health and the health of others." (Anonymous 0236 p. 1)

1. Convene Meetings with the Public

Several commenters (0342, 0295, 0176, 0316) requested that EPA hold meetings with the public.

Friends of the Earth (0342) stated that EPA should:

> "Convene public meetings in the counties where site releases are planned, advertised in the Federal Register, for the review of the company's proposal with the above committee present;" (Friends of the Earth 0342 p. 8)

Friends of the Earth (0342) also stated that:

> "The EPA should also convene public meetings in sites of release as well as the areas surrounding the release site in Florida and Texas. These meetings should be advertised in the Federal Register, and Oxitec's data and EIS should be available for review." (Friends of the Earth 0342 p. 2)

M. Lopez () and J. Barton (0295) stated that:

> "The EPA must convene public meetings in Monroe County, FL (the Florida Keys) and Harris County, Texas, advertised in the Federal Register, for public comment and review of the company's proposal with the above committee present;" (M. Lopez p.1; J. Barton 0295 p. 1)

2. Hold a Referendum

Anonymous (0045) stated that:

> "I reside in Key Haven, Florida. I am asking for another referendum on version 2 GM Mosquito. You can not release without our consent for a newer version with the same problems. We need more time to inform our neighbors to allow them to comment and to vote on being test subjets. I vote NO once again, and ask for more time to make sure our neighbors make informed decisions." (Anonymous 0045 p. 1)[Typographical error in the original]

Anonymous (0322) stated that:

> "Monroe County had a referendum question regarding an Oxitec trial in the Florida Keys in the most recent general election. The data is broken down by precinct, of course. The results are in favor of mosquito trials. I think a trial should take place in those areas that have expressed overwhelming approval of such a test." (Anonymous 0322 p. 1)

F. Comments Arguing that EPA Needs to Develop New Regulations for GE Insects

Several commenters (0295, 0316, 0335, 0342, 0344) argued that EPA needs to develop new regulations for GE Insects. Some commenters argued that only after such regulations are in place should EPA consider applications.

Friends of the Earth (0342) stated that the "EPA should issue new regulations that cover GE mosquitoes before it allows any experimental use of GE mosquitoes", given that:

> "No federal agency has formal regulations specific to GE insects and animals, or law that addresses the risks and all of the types of GE insects. The current U.S. regulatory system is outdated and lacks clear oversight of the use of biotechnology, particularly when it is used for proposals to eliminate insect vectors of animal and human diseases." (Friends of the Earth 0342 p. 5)

Friends of the Earth (0342) further stated that:

> "Regulatory action under the Insecticide, Fungicide and Rodenticide Act (FIFRA) predominantly focuses on the component which would serve as a pesticide, in this case, the tetracycline Trans- Activator Variant (tTAV) protein that Oxitec's GE mosquitoes have been genetically engineered to express. However, it is critical that the EPA examine the whole mosquito, the method of delivery in this case, and its direct and indirect impacts on the environment, human and animal health." (Friends of the Earth 0342 p. 5)

Friends of the Earth (0342) and J. Barton (0295) stated that EPA should:

> "Develop new regulations for genetically engineered insects designed to be biopesticides -- only after these regulations are in place should EPA consider an application for GE insects." (Friends of the Earth 0342 p.2 and p. 8; J. Barton 0295 p. 2)

The Center for Food Safety (0344) and GeneWatch UK (0335) stated that:

> "EPA cannot adequately protect human and animal health and the environment by simply focusing the assessment of risks on the active ingredient tTAV–OX5034 (the genetic sequence which provides the genetically engineered killing mechanism for the mosquitoes). This is because other introduced traits, which are present due to the use of a non-native strain of mosquito (such as altered disease transmission properties), may also pose serious risks to human and animal health and the environment." (Center for Food Safety 0344 p. 2; GeneWatch UK 0335 p. 2)

GeneWatch UK (0335) stated that:

> "Regulatory actions under the Insecticide, Fungicide and Rodenticide Act (FIFRA) focus largely on the active ingredient (intended to act as a pesticide by killing pests), namely the tetracycline Trans- Activator Variant (tTAV) protein that Oxitec's GE mosquitoes have been genetically engineered to express. However, in this case, Oxitec is not releasing an inert ingredient but a living organism. Thus, not only the active ingredient, but also its method of delivery must be carefully considered." (GeneWatch UK 0335 p. 3)

The Center for Food Safety (0344) and GeneWatch UK (0335) also called for the following to be supplied to the public:

> "Published criteria for assessing the impact of existing control measures and the proposed releases on the target pest and the risks of all the relevant diseases." (Center for Food Safety 0344 p. 18; GeneWatch UK 0335 p. 15-16)

J. Ensure Post-Release Control Measures

H. Scott (0052) stated that:

> "These experimental, genetically modified mosquitoes may pose a real risk to human and animal health and safety that may not be currently understood. The anticipation is that these mosquitoes will not be able to reproduce or bite (and thus transmit disease), these claims are NOT proven or guaranteed, and there exists no effective plan to contain or eradicate ALL OX5034 mosquitoes if this were to happen." (H. Scott 0052 p. 1)[Emphasis in the original]

Anonymous (0182) raised the question:

> What if there is a mutated gene sequence and we have GMO mosquito that could cause greater damage to people. If this happens do you have the funds to clean up the mess, much like BP and the spill off the coast in Texas? (Anonymous 0182 p. 1)

Commenter Hasham (0315) questioned:

> Can these genetically modified Mosquitoes be killed later if needed. . . . Who will be held accountable if the results comes out in a disaster?" (Hasham 0315 p. 1)

Anonymous (0173) stated that should be the EUP be granted and testing proceeds:

> " . . . there must be 2 year review period whereas all interested parties must submit proof to support their position and gauge it's impact . . . ." (Anonymous 0173 p.1)

Commenter S.C. Ray (0027) commenting on the Evan et al[NOTEREF _Ref30598723 \h * MERGEFORMAT] article, stated that:

" . . . if this represents a failure of design it needs a coherent mitigation strategy to avoid potentially deleterious and unchecked changes to the genetic makeup of domestic mosquito populations." (S.C. Ray 0027 p. 1)